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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 404

Application Number: 09/258,947
Filing Date: March 01, 1999
Appellant(s): MILLER ET AL.

Karla M. Weyand
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed February 20, 2004.

(1) **Real Party of Interest.**

A statement identifying the real party of interest is contained in the brief.

(2) **Related Appeals and Interferences Identified.**

A statement identifying that no related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) **Status of Claims.**

The statement of the status of claims contained in the Brief is correct.

(4) **Status of Amendments After Final.**

The Appellant's statement of the status of amendments after final rejection contained in the brief is correct.

Appellant's after final amendment filed 2/12/04 has been entered.

(5) **Summary of Invention.**

The summary of invention contained in the brief is correct.

(6) **Issues.**

The Appellant's statement of the issues in the brief is correct.

Upon entry of the after final amendment filed 2/14/04, the previous rejection under the second paragraph of 35 U.S.C. 112 has been withdrawn.

(7) **Grouping of Claims.**

The Appellant's statement in the brief that the claims stand or fall together is agreed with.

(8) **Claims Appealed.**

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) **Prior Art of Record.**

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) **Grounds of Rejection.**

Claims 9 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that the inventor, at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a peptide that inhibits ristocetin induced aggregation of platelets, identified by determining whether the molecule binds to an isolated peptide of SEQ ID NO:174, which may have a three-dimensional structure complementary to the three dimensional structure of the said isolated peptide (Claim 9).

However, Applicant's disclosure is limited to a set of peptides that were developed using the "mimotope decapeptide" (assumed to be SEQ ID NO:1) and includes peptides of SEQ ID NOs: 94-99 and 157-172 of which only SEQ ID NO:94 has been found to inhibit ristocetin induced aggregation of platelets *in vitro* (see page 42, lines 29-32).

The specification fails to describe the requisite structural features of the other peptides that would render the claimed peptides able to inhibit ristocetin induced aggregation of platelets considered the essential feature of the instant invention. Therefore, Applicant (Appellant) has not disclosed sufficient species such that one skilled in the art would conclude that Applicant (Appellant) was in possession of the claimed genus of peptides that bind to SEQ ID NO:174, inhibit ristocetin induced aggregation of platelets, and have the three dimensional structure complementary to the three dimensional structure of the peptide of SEQ ID NO:174.

Consequently, the claimed invention is not described in such a way as to reasonably convey to one of ordinary skill in the art that the inventor, at the time the application was filed, had

possession of the invention, See *Regents of the University of California v. Eli Lilly & Co., 119F3d 1559, 1539, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997)*. Also see the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1st "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

Claims 9 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for SEQ ID NO:94, which inhibits ristocetin induced aggregation of platelets *in vitro* and binds to SEQ ID NO:174, is not enabling for an isolated peptide of 5 to 20 or 20 to 40 amino acids residues in length capable of binding to a second peptide having an amino acid sequence as shown in SEQ ID NO:174, wherein the isolated peptide inhibits ristocetin induced aggregation of platelets, and wherein the isolated peptide has a three dimensional structure complementary to the three dimensional structure of the second peptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation. The specification discloses that SEQ ID NO:94, was found to be just one in a series of 46 similarly isolated clones to inhibit the ristocetin-induced aggregation of platelets *in vitro* (see specification, Figure 8 in particular) suggesting that the ability to bind to the mimotope decapeptide alone is insufficient to predict which peptides are also able to inhibit the ristocetin-induced aggregation of platelets *in vitro*. Further, when SEQ ID NO:94 (RHVAWWRQGV) was modified by one amino acid (SEQ ID NO:104-RHVAWWRQVV) the inhibition of ristocetin-induced aggregation of platelets was slightly reduced, when modified at a second amino acid the inhibition was significantly reduced (SEQ ID NO:106-RHVAWWKQGV), however, when modified at both sites (SEQ ID NO:105-RHVAWWKQVV) the peptide retained potent inhibitory activity (see page 17 and figures 9-11 in particular), suggesting that one skilled in the art would be unlikely to predict which molecules as broadly claimed would bind to SEQ ID NO:174 (WRXXEY), inhibit ristocetin-induced aggregation of platelets and/or have the three dimensional structure complementary to the three dimensional structure of the peptide of SEQ ID NO:174.

The specification fails to provide sufficient guidance or working examples such that one skilled in the art could make and use all molecules as broadly claimed. The specification is silent with respect to specifically which structural elements are critical to the claimed functions and the methods necessary to predict which peptide species would fall within the scope of the claims.

The current state of the art for the prediction of peptide function based on primary structure alone is inadequate (see Mayo). Analysis of the peptide structure alone may help to understand which specific amino acid residues promote a particular function but this is usually not the case (see Mayo, page 214, right column). Furthermore, It is not routine in the art to screen large numbers of peptides to determine which would possess the structural and functional criteria of the claimed molecules based on the instant disclosure. A skilled artisan would require guidance, such as information regarding the amino acid sequences required to preserve the biological, structural or functional features of the peptide in order to use the peptide in a manner reasonably commensurate with the scope of the claims. Therefore, it would take an undue amount of experimentation for one skilled in the art to make and use the peptides in a manner reasonably commensurate in scope with the claimed invention.

(11) Response to Argument

Appellant argues that there are two issues.

Regarding issue one, Appellant argues that, "The specification as filed satisfies the written description requirement for the claims. In particular, page 22, lines 3-12 fully describes an isolated molecule capable of binding to an isolated peptide which comprises an amino acid sequence as shown in SEQ ID NO:174. Further, the specification on page 22, lines 6-11 indicates that the isolated molecule inhibits ristocetin induced aggregation of platelets and has a three dimensional structure complementary to the three dimensional structure of the isolated peptide. Peptides of from 5 to 20 or 20-40 amino acids in length are described on page 14, lines 7-16. Further, a large number of species are listed that define the claimed genus (see specification, page 17, line 23-page 18, line 15). Each of the listed species of peptides is defined as meeting the limitations of the claims. Claim 11 is fully described on page 24, line 33-page 25, line 18."

It is the Examiner's position that the Appellant has merely disclosed the desired properties of the peptides encompassed by the instant claims, not the peptides themselves. The statement that "Each of the listed species of peptides is defined as meeting the limitations of the claims" is factually incorrect. Only the peptide of SEQ ID NO:94 has been shown to both bind the peptide of SEQ ID NO:174 and inhibit ristocetin induced platelet aggregation (see Figure 8). Indeed, as shown in Figure 8 and disclosed at page 42, lines 29-32, the other disclosed peptides which bind the peptide of SEQ ID NO:174 *fail* to inhibit ristocetin induced platelet aggregation. Also note that *none* of the peptides are shown to have three dimensional structure complementary to the three dimensional structure of the peptide of SEQ ID NO:174.

Appellant argues "Applicants submit that the PTO is employing the improper standard in determining whether the application as filed complies the written description requirement of 35 USC 112 (first paragraph)...With particular respect to a claim drawn to a genus, the written description requirement for a claimed genus may be satisfied through description of a representative number of species which have a combination of such identifying, characteristics sufficient to show the applicant was in possession of the claimed genus...In the present patent application, as filed, the claimed invention is described in sufficient detail to allow one of ordinary skill in the art to recognize that applicants had possession of the claimed invention having the distinguishing characteristics of (1)being of 5 to 20 or 20 to 40 amino acid residues in length, (2) capable of binding to SEQ. ID. NO: 174, (3) inhibiting ristocetin induced aggregation of platelets and (4) having a three dimensional structure complementary to the three dimensional structure of the second peptide. Each of the numerous species listed on page 17, line 23 to page 18, line 15 is described as having these distinguishing features."

It is the Examiner's position that the Appellant simply has not described a representative number of species to demonstrate that Appellant was in possession of the claimed genus, particularly as *none* of the disclosed peptides meet all of the limitations of the claims. Additionally, as set forth in *Lilly* and reiterated in University of *Rochester v. G.D. Searle & Co., 69 USPQ2d 1892 (CAFC 2004)*, "A description of what a material does, rather than what it is, usually does not suffice". In the instant case, comprising a "reach-through" situation, the product of the claims is described by what it does (bind the peptide of SEQ ID NO:174 and inhibit ristocetin induced platelet

aggregation), but no meaningful structural characteristics are disclosed. While Claim 9 does recite a three dimensional limitation, no species meeting said limitation are disclosed, nor is it even disclosed how the skilled artisan would establish whether or not the limitation had been met. Accordingly, said limitation cannot be considered a "structural" limitation sufficiently complementing the functional limitation (set forth above) to meet the written description requirement.

Regarding issue two, Appellant argues that, "The present application, as filed, adequately describes how to make and use the present invention. In particular, the specification describes a method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claims without requiring undue experimentation...applicants contend that the identification of peptides that bind to the specifically enumerated mimotope sequence (SEQ ID NO:174) is enabled to one skilled in the art in view of the disclosure in the specification and the state of the art as of the filing date of the subject application"

Appellant argues that, "In particular, the specification, as filed, identifies numerous anti-mimotope sequences (for example, page 17, line 22 to page 23, line 15) which bind to the isolated peptide ... in addition to being limited in regard to the particular mimotope sequence, are also limited to those peptides that inhibit ristocetin induced aggregation of platelets. The identification of such peptides which have this desired functional property can be routinely done using, for example, the methodology disclosed in the specification at page 38, line 13 through page 40, line 20."

It is the Examiner's position that, while peptides which bind SEQ ID NO:174 are disclosed, establishing which of those peptides also inhibit ristocetin induced aggregation of platelets comprises undue experimentation. It is well-established that experimentation without any particular expectation of success (i.e., trial-and-error) is not considered to be routine and indeed, is considered to be undue. In the instant case the specification provides no guidance as to which peptides would likely comprise both functional properties and, as set forth above, Appellant simply indicates that all peptides can be assayed. Indeed, it appears that Appellant used only trial-and-error in the assays of the instant specification as the specification includes no discussion as to why only the peptide of SEQ ID NO:94 (out of some 40+ peptides assayed) meets both binding and inhibiting limitations.

Appellant argues "Lastly, the PTO, in the outstanding office action, indicates that the specification appears to disclose a method that is enabling for producing a peptide which meets the limitations of the claim (Outstanding office action, paragraph 5). Applicants assert, therefore, that the claims to the peptides are, therefore, enabled, because the specification teaches how to make and use them."

It is the Examiner's position that the production of a single peptide does not enable the scope of the claims. The claims encompass peptide of from 5 to 40 amino acids, but just a single peptide of 10 amino acids is disclosed. As mimotopes comprise random three dimensional structures of unpredictable sequence, it is highly unlikely that a peptide of 5 amino acids would have the same three dimensional structure as a peptide of 10 amino acids comprising those same 5 amino acids, nor would a peptide of 10 amino acids have the same three dimensional structure as a peptide of 40 amino acids also comprising those residues. Thus, a single 10 amino acid species cannot enable all of the peptides encompassed by the instant claims. And again, regarding the "complementary three dimensional structure" of Claim 9, it has not been established that even the peptide encoded by SEQ ID NO:94 meets that limitation.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

5/2/04

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